AF/3736

END-712

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Mark Ritchart et. al.	Conf No.	6087
Serial No.:	09/734,787	Art Unit:	3736
Filed :	December 12, 2000	Examiner:	Foreman

For : Method and Apparatus for Automated Biopsy and Collection of Soft Tissue

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APPEAL BRIEF TRANSMITTAL

Dear Sir:

The following revised Appeal Brief is submitted in response to the notice of non conmpliant appeal brief dated April 7, 2005.

Respectfully submitted,

4/14/05

Gerry Gressel
Reg. No. 34,342
Attorney for the Applicants

APPEAL BRIEF

I. REAL PARTY IN INTEREST

The real party in interest is Ethicon Endo-Surgery, Inc., 4545 Creek Road, Cincinnati, Ohio, 45002 (the assignee of the present application).

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that are related to or which will affect or be affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

All the pending claims (Claims 17-22 and 35) stand rejected in a Final Rejection dated 08/16/2004. Claims 11-16 were previously cancelled.

Claims 17-19 and 35 are rejected under 35 USC 102(b) as anticipated by US Patent 2,198,310 to Silverman.

Claim 20 is rejected under 35 USC 103(a) as obvious over US Patent 2,198,319 to Silverman as applied to Claim 17, and further in view of US Patent 4,393,872 to Reznik et al.

Claims 21 and 22 are rejected under 35 USC 103(a) as obvious over US Patent 2,198,319 to Silverman as applied to Claim 17, and further in view of US patent 5,476,101 to Schramm et al.

The appealed claims are Claims 17-22 and Claim 35.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection dated 8/16/04.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent CLAIM 17

Claim 17 recites a method for extracting a tissue sample from a desired site. The claim recites piercing tissue with an instrument, such as assembly 96a which comprises an outer cannula and an inner member having a distal end portion, with the inner member at least partially disposed within the hollow cannula. The outer cannula is illustrated in various embodiments, such as outer cannula 98a (Fig 26); 98b (Fig 29); or 98c (Fig 31), as described from page 25, line 18 to page 27 line 8. The inner member is illustrated in various embodiments, such as inner needle 100a (Fig 26); 100b (Fig 29); or 100c (Fig 31). The method includes the step of positioning the hollow cannula is positioned in tissue at a desired site (See eg. Figs 31-34). The method also includes the step of actuating a first mechanism, which can comprise a spring 116 (e.g. see page 25, line 27), to move the distal end of the inner member distally, relative to the hollow cannula, so that the distal end portion expands radially and engages tissue to be extracted. The step of expanding the distal end portion of the inner member is illustrated in Figures 27, 29, and 33. The method also includes the step of actuating a second mechanism, which can comprise a spring 114 (see e.g. page 26, line 2), to move the outer hollow cannula distally relative to the distal end and to radially retract the distal end portion of the inner member. Finally, the instrument is withdrawn from the tissue with the tissue specimen.

B. Independent Claim 35.

Claim 35 recites a method for extracting a tissue sample from a desired site. The method comprises the step of providing an instrument such as assembly 96a comprising an outer hollow cannula, an inner member having a distal end portion capable of radial expansion, and at least one mechanism (such as spring 116) for moving the outer hollow cannula relative to

the inner member. The outer cannula is illustrated in various embodiments, such as outer cannula 98a (Fig 26); 98b (Fig 29); or 98c (Fig 31), as described from page 25, line 18 to page 27 line 8. The inner member is illustrated in various embodiments, such as inner needle 100a (Fig 26); 100b (Fig 29); or 100c (Fig 31). The method also includes piercing tissue with a distal end of the outer hollow cannula (See Figures 31-34). The method also includes the step of moving the distal end portion of the inner member from a point inside the outer hollow cannula with the at least one mechanism to a position distal of the distal end of the outer hollow cannula to expand the distal end portion of the inner member (see e.g. Figure 27, 29, 33), the step of engaging tissue with the distal end portion of the inner member; and the step of moving the outer hollow cannula relative to the inner member to capture tissue within the distal end portion of the inner member (see e.g. Figures 28, 30, 34).

VI. GROUNDS OF REJECTION

Claims 17-19 and 35 are rejected as anticipated under 35 USC 102(b) by US Patent 2,198,319 (Silverman).

Claim 20 is rejected under 35 USC 103 as obvious over Silverman and further in view of US Patent 4,393,872 (Reznik)

Claims 21 and 22 are rejected under 35 USC 103 as obvious over Silverman and further in view US Patent 5,476,101 (Schramm).

VII ARGUMENT

A. Rejection of Claims 17-19 and 35 under 35 USC 102(b)

Claims 17-19 and 35 are rejected as anticipated by US Patent 2,198,319 (Silverman). It is respectfully urged that this rejection is improper for the following reasons.

Anticipation requires that each and every claim element of the rejected claim be taught by a single prior art reference. It is respectfully urged that Silverman does not teach each and every claim element of Claims 17-19 and 35.

Claim 17 :

With respect to Claim 17, Claim 17 recites, in part:

> actuating a first mechanism associated with the instrument to move the distal end portion of the inner member distally, relative to the outer hollow cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted; and
>
> actuating a second mechanism associated with the instrument to move the outer hollow cannula distally, relative to the distal end portion, to radially retract the distal end portion.

It is respectfully urged that Silverman 2,198,319 does not disclose or suggest actuation of a first mechanism to move the distal end portion of an inner member distally, relative to an outer hollow cannula, so that the distal end portion expands radially and engages tissue.

The Examiner cites col 2, lines 6-9 of Silverman as reciting a first mechanism associated with an instrument to move the distal end portion of the inner member distally. According to the Examiner, the "first mechanism" of Silverman is element 15 of Silverman.

However, it is respectfully urged that this is a mischaracterization of element 15 of Silverman. Element 15 of Silverman is shown and disclosed by Silverman to be an "operating hub" at the end of the interior needle. In other words, element 15 of Silverman is merely an end of the interior needle. It is respectfully urged Silverman does not teach actuation of a mechanism for moving the distal end of an inner member distally relative to the outer hollow cannula, but instead merely teaches that an internal needle can have an end, such as in the form of an operating hub.

It is also respectfully urged that Silverman does not disclose or suggest actuating a second mechanism to move the outer hollow cannula distally, to radially retract the distal end portion of the inner member. It is respectfully urged that the Examiner mischaracterizes element 12 of Silverman as the second mechanism. Element 12 of Silverman is a needle hub of the needle 10. In other words, element 12 is merely an end of the hypodermic needle 10 of Silverman.

The Examiner notes that "mechanism" need only be a piece of machinery. However, it is respectfully urged that Silverman does not teach or suggest the step of actuating a first mechanism as recited in Claim 17, nor actuating a second mechanism, as recited in Claim 17. Operation of the Silverman device is disclosed at lines 1-29 of column 2 of Silverman. It is respectfully urged that, at most, Silverman may viewed as disclosing manual hand operation of the device of Silverman by hand manipulation of the operating hub 15 or needle hub 10. It is respectfully urged that such operation is not properly construed as actuation of a first mechanism, nor actuation of a second mechanism, as set forth in Claim 17.

Claim 35

With respect to Claim 35, Claim 35 recites in part:

> providing an instrument comprising an outer hollow cannula, an inner member having a distal end portion capable of radial expansion, and at least one mechanism for moving the outer hollow cannula relative to the inner member; . . .
>
> . . .

. . . moving the distal end portion of the inner member from a point inside the outer hollow cannula with the at least one mechanism to a position distal of the distal end of the outer hollow cannula . . .

Again, it is respectfully urged that Silverman does not teach or suggest an outer hollow cannula, an inner member having a distal end portion capable of radial expansion, and at least one mechanism. At most, Silverman teaches a hypodermic needle 10 (which the Examiner compares to the outer cannula of Claim 35) and an interior needle having a split end (which the Examiner compares to the inner member of Claim 35). There is no teaching of an additional third element in Silverman, in the form of at least one mechanism for moving the needle 10 of Silverman relative to the inner needle of Silverman. Nor does Silverman teach moving the distal end portion of the inner needle of Silverman with such a mechanism. Accordingly, Silverman does not anticipate Claim 35.

Claim 19:

Claim 19 depends from Claim 17 and recites the step of grasping a tissue sample with a pair of jaws associated with the distal portion of the inner member. Figure 30 illustrates a jaws 142, 144.

The Examiner states that Silverman teaches grasping a tissue sample with a pair of jaws, and refers to Figure 5 of Silverman. It is respectfully urged that this is not a correct characterization of Silverman.

Silverman teaches with reference to Figure 5 at lines 39-50:

"The inner end of the interior needle is split for a goodly portion of its length, i.e., from point to hub, as indicated at 16, the two portions thus formed having divergently pointed and beveled inner extremities 17. The split portions of the interior needle are hollowed on their inner faces, as shown at 18 in Figures 4 and 5."

It is respectfully urged that this disclosure of a split needle of Silverman does not teach or suggest grasping tissue with a pair of jaws, as recited in Claim 19. Instead, Silverman teaches divergently pointed needle portions.

B. Rejection of Claim 20 under 35 USC 103 over Silverman in view of Reznik etal.

Claim 20 is rejected as obvious over Silverman in view of US Patent 4,393,872 to Reznik et al. It is respectfully urged that this rejection is improper for the following reasons.

It is respectfully urged that the Examiner has not met the burden of providing a prima facie case of obviousness. A prima facie case of obviousness requires that three basic criteria be met: 1. There must be some suggestion or motivation in the prior art to modify a reference or combine reference teachings; 2. There must be a reasonable expectation of success; and 3. The references when combined must teach or suggest all the claim limitations. (See MPEP 2143).

Claim 20

Claim 20 depends from Claim 17 and recites the step of grasping a tissue sample with a plurality of hooked extractors associated with the distal end of the inner member. The subject matter of Claim 20 is illustrated in Figures 31-34.

In rejecting Claim 20, the Examiner agrees that Silverman fails to disclose grasping tissue with a plurality of hooked extractors. However, the Examiner urges that it would have been obvious to one of ordinary skill to replace the grasping members as disclosed by Silverman with the hooked extractors as taught by Reznik et al. The Examiner's proposed motivation is that the modification would have been obvious to enable the physician to more readily grasp or grip the target tissue. In support of this conclusion, the Examiner cites Column 3, lines 2-4 of Reznik et al. However, it is respectfully urged that the Examiner has selected a portion of a paragraph in Reznik, while ignoring a portion of the same paragraph that teaches away from the proposed combination.

It is respectfully urged that Column 3 of Reznik et al. does not support the Examiner's proposed combination, but actually teaches away from such a combination. This is because at Column 3, lines 1-6, Reznik et al. explain that the ends of prongs 16a-16d are turned inward, and act to prevent the prongs from being completely withdrawn within the tubular body 12.

Note that in contrast to Reznik et al., Silverman teaches that the inner end of the interior needle is split to have divergently pointed and beveled ends. Silverman goes on to explain the advantage of the divergent, beveled ends by disclosing that the ends of the split inner needle, by reason of their beveled extremeties and because the bevels extend in opposite directions, are caused to be spread apart during insertion of the inner needle, thus assuring the inclusion of a specimen (See Column 2, lines 6-14 of Silverman).

It is respectfully urged that one reading the disclosure of Silverman would not be motivated to replace the divergently beveled split needle portions of Silverman with the inwardly turned prongs of Reznik et al., as proposed by the Examiner. It is respectfully urged that such a modification of Silverman would be counter to the very teachings of Silverman because it would seem that inwardly turned prongs would defeat the very advantage that Silverman seeks to obtain by having divergently pointed and beveled inner needle portions.

It is respectfully urged that one would not be motivated to replace divergent needle portions in a primary reference with inwardly turned (opposite of divergent) ends from a second reference, especially where the primary reference teaches such divergent portions are desirable, and where inwardly turned ends would apparently defeat the very advantage proposed by the primary reference.

Accordingly, it is respectfully urged that the Examiner has not provided a prima facie case of obviousness, and that the rejection should be withdrawn.

C. Rejection of Claims 21 & 22 under 35 USC 103 over Silverman in view of Schramm et al.

Claims 21 and 22 are rejected as obvious over Silverman in view of US Patent 5,476,101 to Schramm et al. It is respectfully urged that this rejection is improper in that the Examiner has not met the burden of providing a prima facie case of obviousness.

Claim 21 depends from Claim 17 and recites that the step of actuating the first mechanism comprises releasing energy stored in a spring element. Claim 22 depends from Claim 17 and recites that the step of actuating the second mechanism comprises releasing energy stored in a spring element.

It is respectfully urged that the Examiner has merely picked various portions from two different prior art references, without regard to teachings in Schramm et al. that would teach away from such a combination.

Schramm et al. '101 does not teach an inner member having a distal portion biased to expand radially at its distal end. Nor does Schramm et al. 101 teach or suggest an inner member distal portion that expands radially as the inner member moves distally relative to the outer member. Rather, Schramm et al. '101 teaches a first needle 86 and a second needle 96. Schramm et al. '101 further states that first needle 86 is a substantially solid shaft 87 with a tissue holding region 90 cut-out from shaft 87. (See Column 11, lines 50-62). It is respectfully urged that the substantially solid shaft 87 of Schramm et al. '101 does not teach or suggest expansion, and that one would not be motivated to make the substantially solid shaft of Schramm et al. expandable.

Nor does Schramm et al. '101 teach or suggest an inner member having a distal end portion that is closed radially by relative movement of the inner member and the outer member.

Further Schramm et al. '101' seems to teach away from the invention as claimed, because Schramm et al. '101' teaches that the inner needle is exposed at all times (see Schramm et al.

'101' at column 12, lines 2-5 and lines 12-18 explaining the point of the inner needle is exposed at all substantial times of operation).

Because Schramm et al. '101' teaches an inner needle with a point that is exposed during operation, it is respectfully urged that one would not be motivated to combine Schramm et al. '101' with Silverman in the manner suggested by the Examiner. Instead, it it is respectfully urged that the Examiner has improperly relied on the Applicants' teachings in hindsight in an effort to modify Silverman with the teaching's of Schramm et al. when Schramm et al. teaches away from the needle configuration sought by Silverman.

Combination would not teach the Claimed Method:

Further, it is not clear how the resulting combination would operate to provide the claimed method. For instance, as noted above, Schramm et al.'s apparatus is configured to have the distal point of the inner needle exposed at substantially all times of operation. So if one did take the spring device of Schramm et al. and place it in Silverman, it is respectfully urged that even if the resulting combination did operate, the resulting device could (depending on how configured) leave the inner needle of Silverman substantially always exposed. In other words, even if one combined the references, it is not clear how the resulting combination would teach the claimed method.

It is respectfully urged that the Examiner has improperly engaged in hindsight reliance on Applicants' specification and improperly picked certain features of Schramm et al, while ignoring others, in an effort to reconstruct the claimed invention.

The Examiner proposes the 1955 decision In re Venner for the proposition that replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. It is respectfully urged that In re Venner does not stand for the proposition that any replacement of a manual operation with an automatic operation is a "design consideration" within the skill of the art. Instead, In re Venner sites an earlier decision for the proposition that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity. (See quote from In re Venner citing In re Rundell, below.)

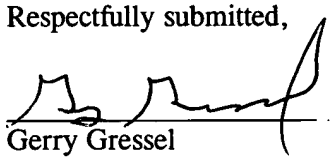
[6] Furthermore, it is well settled that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result. In re Rundell, 18 CCPA 1290, 48 F.2d 958, 9 USPQ 220.

It is respectfully urged that if the Examiner's interpretation of In re Venner were correct, then any invention that replaces a manual method with an automated method would be unpatentable. Additionally it is respectfully urged that the decision in In re Venner does not eliminate the threshold requirement that there be some motivation to combine the references in the manner suggested by the Examiner. It is respectfully urged that Schramm et al. clearly teaches a solid inner needle that is exposed at all times during operation. It is respectfully urged that this not only teaches away from the proposed combination suggested by the Examiner, but also indicates that the "automation" proposed by the Examiner would still not teach the steps set forth in Claims 21 and 22.

Conclusion:

The Board is requested to reconsider the pending claims in light of the above Arguments.

Respectfully submitted,



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Dated April 14, 2005

VII CLAIMS APPENDIX

PENDING CLAIMS

17. A method for extracting a tissue sample from a desired site, the method comprising the steps of:

piercing tissue with an instrument, the instrument comprising an outer hollow cannula and an inner member having a distal end portion, the inner member at least partially disposed within the hollow cannula;

positioning the hollow cannula within the tissue at a desired tissue site;

actuating a first mechanism associated with the instrument to move the distal end portion of the inner member distally, relative to the outer hollow cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted;

actuating a second mechanism associated with the instrument to move the outer hollow cannula distally, relative to the distal end portion, to radially retract the distal end portion; and

withdrawing the instrument, with the tissue sample, from the tissue.

18. The method of Claim 17 wherein the step of piercing tissue comprises piercing tissue with an end portion of the outer hollow cannula.

19. The method of Claim 17 comprising grasping a tissue sample with a pair of jaws associated with the distal portion of the inner member .

20. The method of Claim 17 comprising grasping a tissue sample with a plurality of hooked extractors associated with the distal end of the inner member.

21. The method of Claim 17 wherein the step of actuating the first mechanism comprises releasing energy stored in a spring element.

22. The method of Claim 17 wherein the step of actuating the second mechanism comprises releasing energy stored in a spring element.

35. A method for extracting a tissue sample from a desired site, the method comprising the steps of:

providing an instrument comprising an outer hollow cannula, an inner member having a distal end portion capable of radial expansion, and at least one mechanism for moving the outer hollow cannula relative to the inner member;

piercing tissue with a distal end of the outer hollow cannula;

moving the distal end portion of the inner member from a point inside the outer hollow cannula with the at least one mechanism to a position distal of the distal end of the outer hollow cannula to expand the distal end portion of the inner member;

engaging tissue with the distal end portion of the inner member; and

moving the outer hollow cannula relative to the inner member to capture tissue within the distal end portion of the inner member.

IX. Evidence Appendix:

None

X. Related Proceedings Appendix

None.

GG

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09/734,787	12/13/2000	Mark A. Ritchart	END-712	6087

7590 04/07/2005

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Response Due 5/7/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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PTO-90C (Rev. 10/03)

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 09/734,787	Applicant(s) RITCHART ET AL.
	Examiner Jonathan ML Foreman	Art Unit 3736

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on 24 January 2005 is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file a complete new brief in compliance with 37 CFR 41.37 within ONE MONTH or THIRTY DAYS from the mailing date of this Notification, whichever is longer. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

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